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EXAMINER

NAFF, DAVID M

| ART UNIT | PAPER NUMBER |
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| 1651 | 6 |

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|-----------------|----------------|
| Application No. | Applicant(s) |
| 07/846,842 | Yao <i>shu</i> |
| Examiner | Group Art Unit |
| <i>a/aff</i> | 1657 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 12/3/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-36 is/are pending in the application.

Of the above claim(s) 1, 2, 24 + 27 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 3-25 + 28-30 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other _____

Office Action Summary

In a response of 12/3/02 to a restriction requirement of 9/3/02, applicants elected Group II claims 3-25 and 28-30 with traverse.

In the traverse, applicants urge that examining the claims of the other Groups I and III will not be a serious burden on the examiner.

5 However, due to the differences in the inventions of the different groups as pointed out in the restriction requirement, a serious burden would be on the examiner to examine all claims together of the different groups.

While all claims may require certain components and/or conditions in common, the claims of each group require one or more components and/or 10 conditions that are not common but are specific to the invention of each group. For example, there is no spacer in Group I as in Group II, and in Group III controlling functionalization of a sintered polyolefin is required that is not required in Groups I and II. Therefore, the restriction is adhered to and made final.

15 Claims 1, 2, 26 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4 of 12/3/02.

20 Claims examined on the merits are 3-25 and 28-30.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

25 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-25 and 28-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In claim 3 and where recited in other claims "surface comprises a region defined by at least some of the functional additive" is uncertain as to meaning and scope. It is unclear how the additive defines the region. Does this mean that the functional additive is attached to only a part of the surface without being attached to the entire surface, or
10 something else. Additionally, the meaning and scope of "functional additive" is uncertain. An additive that is functional and not functional is relative and subjective. How the additive functions should be set forth in the claims.

Claims 8 is confusing and unclear by reciting a specific polymer in
15 line 2 in parenthesis after "ketone" in line 1. How the polymer recited in parenthesis is to limit the claim is uncertain.

In claim 13 and where required in other claims, the relationship of the spacer and biological or chemical moiety to the functional additive is unclear. Are the spacer and biological or chemical moiety contained
20 by the region separate from the functional additive or is the spacer and biological or chemical moiety connected to the functional additive in some way.

Claim 14 is confusing by depending on claim 13 which depends on
claim 3, and requiring the porous substrate and biological or chemical
25 moiety to be attached to the spacer. This is not required in claim 3

which requires the spacer to bound to a region and the biological or chemical moiety to be attached to the spacer.

In line 4 of claim 14 and line 3 of claim 17, R and R' are defined. However, Formula I does not contain R and R'.

5 In line 5 of claim 16, line 4 of claim 17, and line 8 of claim 22, it is uncertain as to the form of R³ when in the form of a bond, and how the bond differs from the aliphatic chain that is an alternative to the bond.

Claim 17 is unclear as to the relationship of the spacer to the 10 substrate and functional additive. In the last two lines of claim 17, it is unclear as to what is covalently attached to at least a portion of the functional additive and to the chemical or biological moiety.

Claim 19 is unclear as how the functional additive defines the region, and the relationship of the functional group to the additive.

15 Claim 22 is unclear for the same type of reason as claim 19.

Claim 23 is confusing by not requiring Formula IV to contain a surface as in claim 22 since claim 23 depends on claim 22 and requires modifying the Formula III of claim 22.

To be clear, claim 24 should be amended by after "wherein" in line 20 1, inserting -- X is NH₂ in --, cancel "X is NH₂", and after "and" insert -- the material --.

In Formula VI of claim 24, "R" should be replaced with -- Surface -- to be consistent with Formula III of claim 22 since claim 24 depends on claim 22, and the material of Formula III is contacted with a compound of 25 Formula V to obtain the material of Formula VI.

Claims 28 and 30 are confusing by requiring Formulas VIII and IX to contain R since Formulas VIII and IX are only the formula of the spacer. R is not part of the spacer since it is the surface to which the spacer is attached. When R is present and the spacer is attached to R as in 5 Formulas VIII and IX, the formulas are of the material of claim 13 containing the spacer. It is suggested that "R" be removed from Formulas VIII and IX, and Formulas VIII and IX of the spacer be set forth in the type of way as in claim 14 when defining a formula for the spacer of claim 13.

10

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

15

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20

Claims 3, 5-7, 9-13, 15, 19 and 20 are rejected under 35 U.S.C.

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102(b) as being anticipated by Hendrickson et al (4,855,234).

25

The claims are drawn to a material containing a porous polymer substrate having a surface region defined by a functional additive, a spacer covalently bound to the region, and a biological or chemical moiety covalently or non-covalently bound to the spacer. The spacer may be a silane.

Hendrickson et al disclose preparing a composite article (col 1, lines 11-16) by coating a fibrous support such as made of polyethylene or

polypropylene (col 5, line 51) with a coating solution containing inorganic oxide particles (col 7, lines 41-45 and 55-65, and col 8, lines 46-55) such as silica particles (col 7, line 59), applying a protein immobilizer which can be a silane functional compound (col 6, lines 59-61), and binding a biologically active protein such as an enzyme (col 7, lines 21-41) to the protein immobilizer.

5 The composite article and process for its preparation disclosed by Hendrickson et al are the same as the material presently claimed. The fibrous support is inherently porous polymer substrate, the silica 10 particles are inherently a functional additive defining a surface region of the support, and the silane immobilizer is inherently a spacer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the 15 basis for all obviousness rejections set forth in this Office action:

20 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering 25 patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not 30 commonly owned at the time a later invention was made in order for the

examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson et al in view of Conrad et al (5,773,308).

5 The claim requires a plurality of regions defined by the functional additive.

Conrad et al disclose producing patterned arrays using photoactivatable O-nitrobenzyl polyethylene glycol-silane attached to a substrate. The substrate containing the silane is irradiated through a 10 mask that blocks certain regions of the substrate from being irradiated to result in only certain regions being photoactivated for attachment of an anti-ligand such as an enzyme or antibody (paragraph bridging cols 2 and 3, and col 8, lines 25-45).

It would have been obvious to use as the silane immobilizer of 15 Hendrickson et al the photoactivatable O-nitrobenzyl polyethylene glycol-silane of Conrad et al and form a patterned surface as suggested by Conrad et al.

Claim Rejections - 35 USC § 103

Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being 20 unpatentable over Hendrickson et al in view of Palm et al (6,524,489 B1).

Claim 8 requires the polymer used to form the substrate to be a polyether which is PEEK or PES, and claim 21 requires sintering beads to form the porous substrate.

Palm et al discloses preparing a composite filtration media by 25 blending a functional filtration component such as silica (col 7, line 9)

with a matrix component such as PEEK (col 11, line 4) and sintering to cause agglomeration to occur (col 15, lines 25-30).

It would have been obvious to form the composite article of Hendrickson et al by using PEEK and sintering as taught by Palm et al 5 since this method would have been expected to form the desired composite.

Claim Rejections - 35 USC § 103

Claims 14, 22-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson et al in view of Oka et al 4,897,468) or Ho et al (4,384,045), and if necessary in further view of Yamashita et 10 al (6,004,786).

The claims require a silane spacer having a specific structure.

Oka et al and Ho et al, and if needed Yamashita et al, disclose the type of silanes required by the claims as a coupling agent for immobilizing an enzyme on a carrier. An aldehyde group may be attached 15 to the silane (Oka et al (col 4, line 12) and Ho et al (col 3, line 23)).

It would have been obvious to use as the silane of Hendrickson et al a silane of the type taught by Oka et al or Ho et al, and if needed Yamashita et al, since these silanes would have been expected to provide the function of a silane as disclosed by Hendrickson et al.

20

Claim Rejections - 35 USC § 103

Claims 16, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 14, 22-25 and 28-30 above, and further in view of Nochumson et al (5,552,325).

The claims require the functional additive to be embedded in a surface of the substrate, and a spacer of a specific structure of the type required in claims 14, 22-25 and 28-30.

Nochumson et al disclose a device for selective binding of a 5 biological material such as DNA. The device contains a microporous resinous matrix having particulate binding sites dispersed throughout (col 8, lines 48-67). The dispersed particulate may be silica (col 9, lines 16 and 37) and the matrix may be made of polyethylene or polypropylene (col 8, lines 39-40).

10 When forming the composite of Hendrickson et al with a silane as set forth above, it would have been obvious to disperse the silica particulate within the support as suggested by Nochumson et al since having the silica embedded in the support would have been expected to make the silica more resistant to removal from the support.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

20 If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist
5 whose telephone number is (703) 308-0196.

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DMN
3/5/03



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651